



## VA COOPERATIVE STUDIES PROGRAM # 424

Clinical Outcomes Utilizing Revascularization and Aggressive DruG Evaluation

---

Protocol Amendment No.: 2

**THIS PROTOCOL REPRESENTS A CHANGE TO THE REVISED FEBRUARY 1999 COURAGE PROTOCOL AND SHOULD BE SUBMITTED TO YOUR INSTITUTIONAL REVIEW BOARD/ETHICAL REVIEW COMMITTEE**

The following modification to the protocol has been made at the recommendation of the Data Monitoring Board at its recent meeting on 4/17/00:

Patients who present to the hospital with an acute coronary syndrome (ACS), i.e., with symptoms of “definite” or classic angina, but with no diagnostic ECG changes or abnormal biologic markers at the time of proposed randomization, and without objective evidence of myocardial ischemia (based on objective evidence of myocardial ischemia by either exercise, radionuclear, or pharmacologic criteria within the preceding six [6] months), can be considered trial eligible if ***all*** of the following conditions are met:

1. The ACS can be stabilized with intensive medical therapy;
2. Patients must have a COURAGE-eligible coronary artery with a lesion that is caliper-measured at  $\geq 80\%$  diameter stenosis reduction;
3. All other clinical inclusion and exclusion criteria are satisfied such that the patient is trial-eligible.

Approved by:

\_\_\_\_\_  
William E. Boden, MD  
Study Co-Chairman

\_\_\_\_\_  
Robert A. O'Rourke, MD  
Study Co-Chairman

\_\_\_\_\_  
Pamela M. Hartigan, PhD  
Study Statistician

17 May 2000